DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
1401 Rockville Pike
Rockville MD 20852-1448

Our Reference No. 96-0403 February 11, 1999

Bernardita Mendez, Ph.D.
Chiron Corporation
4560 Horton Street
Emeryville, CA 94608-2916

Dear Dr. Mendez:

The Center for Biologics Evaluation and Research (CBER) has completed a review of your requested supplement to your product license application for Hepatitis C Virus Encoded Antigen (Recombinant/Synthetic)(RIBA), to provide for the manufacture of a Strip Immunoblot Assay including NS5 and c33c recombinant proteins and c100p, 5-1-1p and c22p synthetic peptides to detect antibodies to Hepatitis C Virus in human serum or plasma.

Based upon the information provided to CBER, your request has been found acceptable.

You are requested to submit samples of each future master lot of the product test kit together with protocols consisting of a summary of essential manufacturing data inclusive of all applicable test results. No master lots of the product test kit shall be distributed until notification of release is received from the Director, CBER.

The expiration date of the CHIRON® RIBA™ HCV 3.0 Strip Immunoblot Assay (SIA) cannot be later than that of the shortest dated component, which is the Coated Strips or the Conjugate, which have an expiration date of 14 months from the date of manufacture when stored at 2-8°C. Any request to extend these dating periods must be accompanied by the results of ongoing stability studies.

Any lot of the CHIRON® RIBA™ HCV 3.0 Strip Immunoblot Assay (SIA) found to fall outside of the approved specifications, including the expiration date, should be withdrawn from the market. In addition, any reports of significant product defects or product complaints concerning the use of this product should be submitted to the Office of Compliance, CBER, HFM-650.

A review of labeling has been sent under separate cover. Please submit two (2) copies of final printed labeling at the time of use and include Part II of the Transmittal of Labels and Circulars form (Form FDA-2567) with completed implementation information.

In addition, please submit three (3) copies of the proposed introductory advertising and promotional labeling. You may wish to submit the proposed material in draft form with Part I of FDA Form 2567 to CBER, Advertising and Promotional Labeling Staff (APLS), HFM-602, 1401 Rockville Pike, Rockville, Maryland 20852-1448. Promotional claims should be consistent with and not contrary to the approved labeling. No comparative claims or claims of superiority over other similar products should be made unless data to support such claims are submitted to and approved by CBER. Final copies of advertising and promotional materials should be submitted at the time of use with Part II of FDA Form 2567 to APLS. Please include copies of the approved labeling with your advertising and promotional materials.

This information will be placed on file with your product license application for Hepatitis C Virus Encoded Antigen (Recombinant/Synthetic)(RIBA).

Sincerely yours,

Jay S. Epstein, M.D.
Director
Office of Blood Research and Review
Center for Biologics Evaluation
and Research